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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,534	03/12/2004	Long Sheng Yu	76982-Z/JPW/JSW	7819
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COOPER & DUNHAM, LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,534	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

As to claim 12, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an inflow tube at a range of longitudinal position) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, claims 12-13 stands rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation of "an adjustable attachment member to permit attachment.... a range of longitudinal position". There is not support in the specification for a range of longitudinal positions for an attachment member.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Mussivand et al. (US 6,290,639). Mussivand et al. discloses a conduit assembly in figure 1 and 2A. As seen in figure 1, the system includes a VAD 2 as a pump portion, an inflow tube protruding from the pump and an adapter sleeve. The inflow tube and adapter sleeve can be seen more clearly in the replication of figure 2A below.



In figure 2A, the inflow tube is depicted as portion B and the adapter is depicted as portion A, as indicated accordingly. Also depicted is a sewing ring or skirt 118 and an inflow port extension 6a, which the examiner considers to be an inner sleeve that extends inside the inflow tube. Additionally, “material of rigid components, it is preferable to use titanium”(col.7, lines 56-57) and as seen in the figures, the sleeve is smooth.

2. Claims 1-3 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kahn et al. (US 3,766,567). Kahn et al. discloses an artificial heart assembly that is connected to the ventricular apex of the heart, as seen in figure 8. Also depicted in figure 8 is the pump 20, inflow adapter 88 which the examiner considers the inflow tube, tubular extension 86 which the examiner considers to be an adapter sleeve, and arterial grafting tubing 87 which the examiner considers to be the adjustable attachment member.

Furthermore, since the “arterial graft tubings 87 and 92 are made of flexible, non-collapsing materials, for example, spirally wound metal wire covered with silicone” (col. 6, lines 37-39) they are thus flexible and compressible or extendable in a range of longitudinal positions.

As to claims 2-3 and 7, also seen in figure 8 is the sewing flange 76. Furthermore, the examiner considers the sewing ring to function as a gripping member to attach the inflow tube to the ventricular apex.

As to claim 8, as seen in figure 8, since the inlet and outlet of the inflow tube are at different angles, there is necessarily a bend in the tube.

As to claims 9-10, “built into the assist adapters 88 and 89 are connectors 90 and 91 like the connector 22 of FIGS. 6 and 7 for easy attachment to the connectors 23 and 27 on the ventricle 11”(col. , lines ). Thus the end of inflow tube 88 that connects to connector 90 is extendable, as seen in figures 6 and 7.

As to claim 11, figure 6 discloses a valve 21, which the examiner considers to be an inner sleeve.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 4, 6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (US 3,766,567). Kahn et al. discloses the claimed invention but does not disclose expressly the titanium or ceramic material. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the adapter sleeve as taught by Kahn et al., with a titanium or ceramic adapter sleeve, because Applicant has not disclosed the titanium or ceramic material provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the adapter sleeve as taught by Kahn et al., because both materials are biocompatibility and frequently incorporated in implantable devices.

Therefore, it would have been an obvious matter of design choice to modify the material for titanium to ceramic to obtain the invention as specified in the claim(s).

Furthermore, Kahn et al., discloses the claimed invention except for the titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material to ceramic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (US 3,766,567). Kahn et al. discloses the claimed invention except perforations on the adapter sleeve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kahn et al. with grooves forming perforations in order to provide the predictable results of customizing the size of the adapter sleeve in order to modify the device to meet specific patient needs. For example, a child may need an adapter that differs in size than an adult.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
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